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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,859	03/19/2004	John Mattick	DAVI199.005CP1	7975
20995 7590 03/26/2008 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER DEJONG, ERIC S	
			ART UNIT 1631	PAPER NUMBER
			NOTIFICATION DATE 03/26/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/804,859	Applicant(s) MATTICK ET AL.	
	Examiner ERIC S. DEJONG	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2007 and 20 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-21,23-48,53-59 and 61 is/are pending in the application.
- 4a) Of the above claim(s) 7,10,16-18,24,26,32-34,37,40,46-48 and 53-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,8,9,11-15,19-21,23,25,27-31,35,36,38,39,41-45 and 61 is/are rejected.
- 7) ☒ Claim(s) 35 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>02/22/2005 and 03/20/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicants response filed 04/20/2007 is acknowledged.

Applicants amendment to the specification, filed 08/20/2004 is acknowledged.

Election/Restrictions

The previous objection to claim 4 under 37 CFR §1.75(c) as being in improper form is withdrawn in view of amendments made to the instant claim, filed 01/10/2007. It is further acknowledged that claim 4 is now in proper form depending from either claim 1 or 2 and has been included in Group I (see the restriction requirement, mailed 10/12/2006).

Applicant's election of Group I (Claims 1-48 and 61), Species A (claims 6, 23, and 36), and Species C1 (claims 9, 11, 15, 25, 27, 31, 39, 41, and 45) in the reply filed on 04/26/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-4, 6-21, 23-48, 53-59, and 61 are pending. Claims 5, 22, 49-52, and 60 are canceled. Claims 7, 10, 16-18, 24, 26, 32-34, 37, 40, 46-48, and 53-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 04/26/2007. Claims 1-4, 6, 8, 9, 11-15, 19-21, 23, 25, 27-31, 35, 36, 38, 39, 41-45, and 61 are currently under examination.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and /or amino acid sequences set forth in CFR § 1.821(a)(1) and (a)(2). The requirements of CFR § 1.821 through 1.825 requires a submission of a computer readable form sequence listing, a paper copy for the specification, a statement under CFR § 1.821(f) and (g), and SEQ ID numbers cited along with each sequence in the specification ***or Figures*** (emphasis added). Applicants submission of a computer readable form sequence listing, a paper copy for the specification, and a statement under CFR § 1.821(f) and (g), filed 03/19/2004 and 08/20/2004, is acknowledged, however Figure 6 contains a sequence which is not identified with a SEQ ID No. nor accompanied by a corresponding SEQ ID No. in the brief description on page 12, lines 28-30 of the instant specification. Applicants are also reminded that SEQ ID numbers are not required in the Figures per se, however, the corresponding SEQ ID numbers then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD_ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in

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abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

Information Disclosure Statement

The listing of references in the specification on pages 74-86 is not a proper information disclosure statement (IDS). 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or included on an IDS form initialed and signed by the examiner, they have not been considered.

The information disclosure statements submitted on 02/22/2005 and 03/20/2007 have been being considered by the examiner in full.

Specification

The abstract of the disclosure is objected to because it contains more than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Objections

As noted above, it is reiterated that the objection to claim 4 under 37 CFR §1.75(c) as being in improper form is withdrawn in view of amendments made to the instant claim, filed 01/10/2007.

Claims 35 and 38 is objected to because of the following informalities:

Claim 35 recites in line 4 "up-or down-regulate" and should be amended to include a space and reads as --up- or down-regulate--.

Claim 38 recites in lines 1 and 2 "wherein the receiver DNA is RNA is located" and should be amended to recite --wherein the receiver DNA is located--.

Appropriate corrections are required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 4, 6, 8, 9, 11, and 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 3, 4, 6, 8, 9, 11, and 15 are drawn to a process for identifying an eRNA or a DNA sequence comprising an eRNA-encoding sequence in the nucleome of a eukaryotic cell. The recited method involves abstract process steps of identifying non-protein encodings sequences, determining the nucleotide sequence of said non-protein encoding nucleotide sequence, and determining the degree to which said sequences is

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conserved wherein a non-protein encoding nucleotide sequences conserved within a genome or between different cells' nucleosomes is deemed to be an eRNA or a eRNA encoding DNA sequence and, therefore, involves the application of a judicial exception. Regarding inventions involving the application of a judicial exception, said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999))). In the instant claims, there is no step of physical transformation that results from said application of judicial exception, thus the Examiner must determine if said application of a judicial exception produces a useful, concrete, and tangible result.

A tangible result requires that the claim must set forth a practical application of a judicial exception to produce a real-world result. Claims 1, 3, 4, 6, 8, 9, 11, and 15 do not produce a tangible result because the result produced by practicing the recited abstract process steps is a determination of an eRNA or eRNA encoding DNA sequence that is neither isolated or synthesized (in a physical context) nor further output or displayed to a user (in a computational context). For the benefit of applicants, an amendment to the instant claim so as to recite that an identified eRNA or eRNA encoding DNA sequence is further synthesized or, alternatively, is further output or displayed to a user would be sufficient to overcome the instant rejection, provided that the instant specification has written support for such an amendment.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 8, 9, 11-15, 19-21, 23, 25, 27-31, 35, 36, 38, 39, 41-45, and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to use the claimed invention one of skill in the art must identify an eRNA or a DNA sequence comprising a nucleotide encoding an eRNA from conserved non-protein encoding sequences within a genome or between different cells' nucleosomes. Further, as instant claimed, one of skill in the art must conclude that any non-protein encoding DNA sequence within a genome or any non-protein encoding

region of an RNA transcript must be an DNA sequence encoding an eRNA or an eRNA, respectively, when said non-protein encoding sequences are determined to be conserved either within a cell's genome, in the genome of other species, or in the genera of eukaryotic cells. For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The instant specification describes known instances non-protein encoding regions within an RNA transcript or a DNA sequence comprising non-protein encoding nucleotide sequences that function as network control molecules in higher organisms. The instant specification does not provide detailed guidance for determining what non-protein encoding regions within an RNA transcript or DNA sequences comprising non-protein encoding regions are eRNAs or are DNA sequences that encode an eRNA, respectively, based only on a determination of sequence conservation.

c) The instant specification does not provide any working example wherein an eRNA or a DNA encoding an eRNA was identified by sequence conservation alone. Further, the instant specification lacks clear evidence that all conserved non-protein encoding regions of DNA sequence or RNA transcripts either code for or are eRNAs, respectively.

d) The nature of the invention, identifying eRNA from non-protein encoding nucleic acid regions, is complex.

e) The prior art does not show that all conserved non-protein coding regions of RNA transcripts are eRNAs nor that all conserved non-protein coding regions of DNA sequences encode for eRNA. Erdmann et al. (Nucleic Acids Research (2001) Vol. 29,

pages 189-193, see the IDS filed 03/20/2007) discloses a non-coding RNAs database comprising currently available data on RNAs that act as riboregulators (see Erdmann et al., Abstract and throughout). Erdmann et al. does not teach that all conserved non-protein coding regions of RNA transcripts are eRNAs nor that all conserved non-protein coding regions of DNA sequences code for eRNAs. Hamilton et al. (Science (1999), Vol. 286, pages 950-952, see IDS filed 03/20/2007) teaches species of small antisense RNA involved in posttranslational gene silencing (PTGS) (see Hamilton et al., Abstract and throughout). Hamilton further teaches that though PGTS-specific antisense RNA may exist, that are not easily detected and have not been readily detected using routine RNA analysis (see Hamilton et al., page 950, col. 1, line 20 through col. 3, line 11). Mattick et al. (EMBO Reports, Vol. 21, pages 986-991, see IDS filed 03/20/2007) proposes the central dogma is incomplete and that intronic and other non-coding RNAs have evolved to comprise a second tier of gene expression in eukaryotes (see Mattick et al., Abstract). Mattick et al. further describes known instances of intronic and other non-protein coding RNAs that contain functional information (see Mattick et al., page 988, col. 1, line 27 through col. 2, line 8). Mattick further predicts that the vast majority of non-coding RNAs have yet to be catalogued (see Mattick et al., page 988, col. 2, lines 9-23). Mattick et al. does not teach that any and all conserved non-protein coding regions of RNA transcripts are eRNAs nor that any and all conserved non-protein coding regions of DNA sequences encode for eRNA.

f) The skill of those in the art of identifying eRNA from non-protein encoding nucleic acid sequences is high.

g) The predictability of the relationship that all conserved non-protein encoding regions of nucleic acids either encode for or are eRNAs is unknown in the prior art.

h) The claims are broad in that any non-protein encoding region of any RNA transcript or any non-protein encoding region of any DNA sequence that is conserved in any cell's genome, in any genome of other species, or in the genera of eukaryotic cells is deemed to either be (in the case of RNA) an eRNA or encode for (in the case of DNA) an eRNA.

The skilled practitioner would first turn to the instant specification for guidance in using the claimed invention. However, the instant disclosure lacks clear evidence that eRNA can be identified from conserved non-protein encoding nucleic acid sequences within in a cell's genome, in the genome of other species, or in the genera of eukaryotic cells. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art does not show that all conserved non-protein coding regions of RNA transcripts are eRNAs nor that all conserved non-protein coding regions of DNA sequences encode for eRNA. Finally, said practitioner would turn to trial and error experimentation to determine a relationship between conserved non-protein encoding nucleic acid sequences amongst a cell's genome, in the genome of other species, or in the genera of eukaryotic cells so as to identify an eRNA or a DNA sequence that encodes an eRNA. Such amounts to undue experimentation.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 6, 8, 9, 11-15, 19-21, 23, 25, 27-31, 35, 36, 38, 39, 41-45, and 61 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Claims 2 and 19 each recite the process steps of identifying and determining an eRNA or a DNA sequence encoding said RNA (see for example, lines 3-13 of claim 2 and lines 3-13 of claim 19) and, further, contacting said eRNA with nucleome and proteome material (as in claim 2, line 15) or proteome material (as in claim 19, line 15). However, said claims omit the essential process steps wherein an eRNA is either isolated or synthesized, following the above described abstract identifying and determining steps, for use in the above described physical contacting step. Such amounts to a gap between the recited process steps. Claims 3, 4, 6, 8, 9, 11-15, 20, 21, 23, 25, 27-31, 35, 36, 38, 39, 41-45, and 61 are also included under this rejection due to their dependence from either of claims 2 or 19.

Claims 1-4, 6, 8, 9, 11-15, 19-21, 23, 25, 27-31, 35, 36, 38, 39, 41-45, and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said non-protein-encoding nucleotide sequence" (singular) in lines 7 and 8. There is insufficient antecedent basis for this limitation in the claim as lines 4 and 5 recite the limitation "non-protein-encoding nucleotide sequences" (plurality).

Claim 2 recites the limitation "said non-protein-encoding nucleotide sequence" (singular) in lines 6 and 7. There is insufficient antecedent basis for this limitation in the claim as lines 3 and 4 recite the limitation "non-protein-encoding nucleotide sequences" (plurality).

Claim 19 recites the limitation "said non-protein-encoding nucleotide sequence" (singular) in lines 6 and 7. There is insufficient antecedent basis for this limitation in the claim as lines 3 and 4 recite the limitation "non-protein-encoding nucleotide sequences" (plurality).

Claims 3, 4, 6, 8, 9, 11-15, 20, 21, 23, 25, 27-31, 35, 36, 38, 39, 41-45, and 61 are also included under these rejections due to their dependence from either of claims 1, 2, or 19.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Moran Marjorie can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
Art Unit 1631

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